DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
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February 20, 2015

i-codi Co., Ltd.
Mr. Bret Andre,
Official Correspondent, i-codi
EyeReg Consulting, Inc.
474 NE 61st Pl
Hillsboro, Oregon 97124

Re: K143431
Trade/Device Name: Giselle (polymacon) Daily Wear Soft (hydrophilic) Contact Lenses (Clear and Tinted)
Regulation Number: 21 CFR 886.5925
Regulation Name: Soft (Hydrophilic) Contact Lens
Regulatory Class: Class II
Product Code: LPL, MVN
Dated: January 21, 2015
Received: January 23, 2015

Dear Mr. Andre:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR

Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Kesia Y. Alexander -S

for Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic and Ear, Nose,
and Throat Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K143431

Device Name
Giselle (polymacon) Daily Wear Soft (hydrophilic) Contact Lenses (Clear and Tinted)

Indications for Use *(Describe)*
The Giselle (polymacon) Spherical Soft Contact Lenses for daily wear are indicated for the correction of visual acuity in aphakic and not aphakic persons with non-diseased eyes with myopia or hyperopia. The lens may be worn by persons who exhibit refractive astigmatism of 0.50 diopters or less where the astigmatism does not interfere with visual acuity. The lens is available clear or tinted and may be used to enhance or alter the apparent color of the eye.

Daily wear replacement schedules may vary from patient to patient and should be decided by eyecare practitioners in consultation with their patients.

Frequent/Planned Replacement Wear:
Eyecare practitioners may prescribe any of the above lenses for frequent/planned replacement wear, with cleaning disinfection and scheduled replacement. When prescribed for frequent/planned replacement wear, the lens may be disinfected using a chemical disinfecting system.

Disposable Wear:
Eyecare practitioners may prescribe any of the above lenses for Daily Disposable Wear. When Prescribed for Daily Disposable Wear the lenses are not to be used with disinfecting systems as they are to be discarded after a single use.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510 (k) SUMMARY OF SAFETY AND EFFECTIVENESS

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is: K143431

Applicant information:

Date Prepared:	11/25/2014
Name:	**i-codi Co., Ltd.** #959-9, Daechon-Dong, Buk-Gu, Gwangju South Korea
Contact Person:	Park, Yoo Hwan President
Phone number:	+82-10-5237-4746
Consultant:	Bret J Andre EyeReg Consulting, Inc. 474 NE 61st PL Hillsboro, OR 97124 United States
Phone number:	(503) 372-5226

Device Information:

Device Classification:	Class II
Product Code:	LPL; MVN
Classification Name:	Soft (hydrophilic) Contact Lens (21 CFR 886.5925)
Trade Name:	**Giselle (polymacon) Daily Wear Soft (hydrophilic) Contact Lenses (Clear and Tinted)**

Equivalent Devices:

Giselle (polymacon) Daily Wear Soft (hydrophilic) Contact Lenses (Clear and Tinted) are substantially equivalent to the following predicate devices:

Predicate devices:

- **"VASSEN COLOR"**
  By Vassen Co., Ltd.
  510(k) number; K141699

Device Description:

The **Giselle** soft contact lenses are hemispherical shells with molded spherical base curves and molded front surfaces. The **Giselle** soft contact lenses are fabricated from polymacon, which in the dry (unhydrated) state may be machined and polished. The hydrophilic nature of this material allows the lens to become soft and pliable when immersed in an aqueous solution.

The nonionic lens material, (polymacon) is a hydrophilic polymer of 2-Hydroxyethyl methacrylate (2-HEMA) and cross-linked with ethylene glycol dimethacrylate (EGDMA), plus an initiator. The co-polymer consists of 62% polymacon and 38% water by weight when immersed in saline solution. The (polymacon) name has been adopted by the United States Adopted Names Council (USAN).

Giselle lenses are available clear, visibility tinted, and tinted to enhance or alter the apparent color of the eye (opaque tinted lenses). Clear or tinted lens designs may be distributed under unique or "private label" trade names. **Giselle** lenses are tinted with one or a combination of one or more of the following 'listed' color additives: D&C Yellow 10, D&C Green 6, Titanium Dioxide, Iron Oxide (Red), C.I. Reactive Blue 19, and C.I. Reactive black 5. Lenses that contain a unique tinting pattern are subsequently processed to incorporate the 'listed' color additives, and contain only the amount of color additive needed to accomplish the intended coloring effect. When producing the opaque tinted lenses, the manufacturing process alters and/or changes the specifications to the clear version of a contact lens via entrapment of a listed color additive in the center of the contact lens (between layers of contact lens material) in a location that corresponds to the iris. The color additives used are not removed by lens handling and cleaning/disinfecting procedures. Except for affecting the amount of light transmittance through the lens, the coloring process does not alter the original characteristics of the pre-tinted lens. The opaque tinting pattern has a minimum clear pupil diameter of 6.0 mm.

In the hydrated state, the lens conforms to the curvature of the eye covering the cornea and extending slightly beyond the limbus forming a transparent or colored optical surface. The (polymacon) soft hydrophilic contact lens has a spherical back surface. The hydrophilic properties of the lens require that it be maintained in a fully hydrated state in a solution compatible with the eye. If the lens dries out, it will become hard and appear somewhat warped; however, it will return to its proper configuration when completely rehydrated in the proper storage solution.

The physical properties of the lens are:

Refractive Index	1.439
Light Transmission (clear)	greater than 95%
Light Transmission (tinted)	greater than 95% (at clear region corresponding to pupil, minimum 6.0 mm diameter); Opaque or 0-10% (at tinted region corresponding to iris)
Surface Character	hydrophilic
Water Content	38±2%
Specific Gravity	1.18 (hydrated)
Oxygen Permeability	10.55 (cm^2/sec)(mlO_2)/(ml x mmHg @ 35°C)) (revised Fatt method)

The hydrophilic characteristics allow aqueous solution to enter the lens, and in its fully hydrated state the lens is approximately 38% water by weight. The lenses will be manufactured in the spherical configuration with the following features and properties:

Chord Diameter:	13.00 mm to 15.00 mm
Center Thickness:	0.06 mm to 0.17 mm
Base Curve:	8.0 mm to 9.0 mm
Power Range	-10.00D to +3.00D in 0.25D steps

Giselle lenses are supplied sterile in saline solution containing blister packages with a base made from polypropylene and a laminated foil seal on top. Blister package labeling is printed with the appropriate lot numbering, expiration dating, and lens parameter identification. Expiration dating has been established based on studies of product stability, package integrity, and validation of the sterilization process.

Intended Use:

The **Giselle (polymacon) Spherical** Soft Contact Lenses for daily wear are indicated for the correction of visual acuity in aphakic and not aphakic persons with non-diseased eyes with myopia or hyperopia. The lens may be worn by persons who exhibit refractive astigmatism of 0.50 diopters or less where the astigmatism does not interfere with visual acuity. The lens is available clear or tinted and may be used to enhance or alter the apparent color of the eye.

Daily wear replacement schedules may vary from patient to patient and should be decided by eyecare practitioners in consultation with their patients.

Frequent/Planned Replacement Wear:

Eyecare practitioners may prescribe any of the above lenses for frequent/planned replacement wear, with cleaning disinfection and scheduled replacement. When prescribed for frequent/planned replacement wear, the lens may be disinfected using a chemical disinfecting system.

Disposable Wear:

Eyecare practitioners may prescribe any of the above lenses for Daily Disposable Wear. When Prescribed for Daily Disposable Wear the lenses are not to be used with disinfecting systems as they are to be discarded after a single use.

Testing:

Non-clinical Testing

A series of in vitro and in vivo preclinical toxicology and biocompatibility tests were performed to assess the safety and effectiveness of the **Giselle** (polymacon) Daily Wear Soft (hydrophilic) Contact Lenses packaged in blister packages. All non-clinical toxicology tests were conducted in accordance with the GLP regulation. All other testing was conducted according to valid scientific protocols.

Test results of the non-clinical testing on the **Giselle** (polymacon) Daily Wear Soft (hydrophilic) Contact Lenses demonstrate that:

- Lenses supplied in blister packages and glass vials are sterile for the indicated shelf-life,
- The packaging material and extracts are not toxic and not irritating, and
- Lens physical and material properties are consistent with currently marketed lenses.

Clinical Data

The clinical performance of the (polymacon) lens material has been previously established, and therefore was not required for this 510(k).

Conclusions Drawn from Studies

Validity of Scientific Data

Several laboratories under Good Laboratory Practice regulations conducted toxicology studies, microbiology, chemistry, shelf-life stability studies and followed scientific protocols. The data were determined to be scientifically valid under 21 CFR 860.7

Substantial Equivalence

Information presented in this Premarket Notification establishes that the **Giselle,** (polymacon) Soft Contact Lenses for Daily Wear is as safe and effective as the predicate device when used in accordance with the labeled directions for use and for the requested indication.

Risks and Benefits

The risks of the subject device are the same as those normally attributed to the wearing of daily wear soft contact lenses. The benefits to the patient are the same as those for other daily wear soft contact lenses.

Substantial Equivalence:

The **Giselle** Soft Contact Lens will be manufactured according to specified process controls and a cGMP quality assurance program currently in place. The established safety profile (pre-clinical toxicology and manufacturing/chemistry data) of the **Giselle** contact lens material is equivalent to the predicate devices identified previously. Being similar with respect to indications for use, materials, physical construction and safety & effectiveness to the predicate devices, this meets the requirements per section 510(k) of the act regarding substantial equivalence and *does not raise* different questions of safety and effectiveness than the predicate device identified above.

The following matrix illustrates the equivalencies of the **Giselle** Soft (hydrophilic) Contact Lens, as well as the substantial equivalent predicate devices.

Substantial Equivalence Matrix

	I-Codi Co., Ltd. Giselle (polymacon) New Device	**Vassen Co., Ltd. VASSEN COLOR (polymacon) Predicate Device**
Intended Use	Indicated for daily wear for the correction of visual acuity in aphakic and not aphakic persons with non-diseased eyes with myopia or hyperopia and/or possesses refractive astigmatism not exceeding 0.50 diopters.	Indicated for daily wear for the correction of visual acuity in aphakic and not aphakic persons with non-diseased eyes with myopia or hyperopia and/or possesses refractive astigmatism not exceeding 0.50 diopters.
Functionality	Same as predicate device	Same as predicate device
Indications	Daily Wear, Soft (hydrophilic) Contact Lens	Daily Wear, Soft (hydrophilic) Contact Lens
Production Method	Fully-molded	Fully-molded
USAN name	polymacon	polymacon
Water Content (%)	38±2%	38±2%
Oxygen Permeability	10.55×10^{-11} (cm^2/sec)(mlO_2)/(ml x mmHg @ 35°C)) (revised Fatt method)	10.55×10^{-11} (cm^2/sec)(mlO_2)/(ml x mmHg @ 35°C)) (revised Fatt method)
Specific Gravity	1.18 (hydrated)	1.18 (hydrated)